Surgeon General's Media Update

Jan. 11, 2007

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But some soldiers are using the Hemcons, which cost \$120 each, the wrong way, according to medics and military doctors.

Some soldiers are plastering Hemcons on wounds where they can't stick. And others are using them almost as casually as Band-Aids, according to Capt. Gerald W. Surrette, a doctor who is brigade surgeon of the 2nd Brigade Combat Team, 2nd Infantry Division.

The bandage's cost isn't the issue, Surrette said. It's a matter of saving lives.

Fifty percent of all combat deaths, including those in Iraq, are caused by uncontrolled bleeding, according to statistics collected by the U.S. Army and provided by Surrette.

A large proportion of those deaths are immediate and unpreventable by anyone, including the most skilled surgeons in the world, Surrette said. But nine percent of troops who have died in Iraq have died from uncontrolled bleeding to arms or legs, he said.

"And those (kinds of deaths) are potentially preventable," he noted. "We can do something about those, if every single Joe could be trained" to respond correctly on the battlefield.

In the effort to train and equip "every single Joe," to save those lives, the best way to look at the Hemcon is "as another tool in your tool chest," Surrette said.

Medically speaking, "there's maybe one percent of the time" that the Hemcon bandage is the best possible option to use on a combat wound, he said.

"It's way down the line of what you should reach for," Surrette said. "The first thing you should reach for as you run to a patient should be your tourniquet."

The Hemcon was developed by the Army's Institute of Surgical Research at San Antonio, and named as one of the Army's top 10 inventions in 2004.

The Army began to issue one Hemcom bandage to each deployed soldier just last year. There seems to be some confusion out there about how the bandages are supposed to be used, Surrette and his medics said.

Aid station medics and physicians at Forward Operating Base Loyalty in Baghdad have seen soldiers come in with Hemcons applied to wounds where direct pressure would have done a much better job controlling the bleeding. They've even been applied to relative scratches.

Then there are soldiers who look at the Hemcon's thin, flat appearance and think it's supposed to stick to skin and hold the edges of wounds together. That's totally wrong, too, medics say.

On the other hand, military medics want to make sure soldiers don't regard the Hemcons as some kind of quick fix that can simply be slapped on and solve all kinds of major combat trauma.

They shouldn't be thought of as a cure-all, said Cpl. Heaven Gallop, 27, of Winston-Salem, N.C., a medic for the 2nd Infantry Division's Headquarters Headquarters Company, 2nd Brigade Special Troops Battalion.

The Hemcon bandage is made from chitosan, a substance contained in shellfish shells. It works by reacting with blood and provoking a clotting reaction, which helps stop bleeding.

"But if there isn't enough blood, the chitosan on the Hemcon bandage won't have anything to react with," said Spc. Mark Duchesneau, 33, of Boston, another FOB Loyalty medic with the 2nd Battalion, 17th Field Artillery. "It won't work if all it's in contact with is skin. You have to really force it in there."

The bandages are flexible and can be rolled, bent or even cut if necessary to fit into slashes and cuts, he said.

Hemcons also can be very useful in helping to control bleeding in situations where a soldier has severed an artery high in the groin or very high under the armpit, for example, the medics said.

In those kinds of wounds, tourniquets can be difficult or impossible to apply, and direct pressure doesn't always work because it's hard to find the right spot to make the bleeding stop, Surrette said.

Hemcons can also help control abdominal bleeding, another place where a tourniquet can't go.

Surrette said he has spent a lot of time training brigade soldiers on the proper use of the Hemcon bandage, and as a result, its casual use has dropped dramatically.

It's important for soldiers to know what's going to work best under fire, and that's tourniquets and pressure, then a Hemcon bandage, Surrette said.

But "you do whatever you have to do to stop the bleeding," he said. "I will never second-guess them. ... I just tell them to keep the blood in, and get them to me."

Akaka takes over helm of VA committee The Senator is expected to raise the VA profile in Hawaii 01/10/07 - By Richard Borreca, The Honolulu Star-Bulletin

WASHINGTON » U.S. Sen. Daniel Akaka is the first of a trio of Hawaii congressmen to take control of a committee or subcommittee on the new Democratic-controlled Capitol Hill.

Yesterday Akaka took over as chairman of the Senate Veterans Affairs Committee. He has been a member of the committee since 1990. Before Democrats assumed the majority, Akaka was the Democrat with the most seniority on the 14-person committee.

U.S. Sen. Daniel Inouye is set to take over as chairman of the Commerce, Science and Transportation Committee and the Defense Appropriations Subcommittee.

U.S. Rep. Neil Abercrombie is going to become chairman of a subcommittee on the Army and Air Force.

Yesterday's Senate meeting to organize the Veterans Affairs Committee featured the passing of the gavel from Sen. Larry Craig, R-Idaho, to Akaka.

Recalling how last year the committee "was forced to cobble together a final legislative package ... in 48 hours," Akaka said he wanted to finish its work for the year by June.

The first hearings, set for later this month, will deal with how the departments of Veterans Affairs and Defense work with those leaving the armed services, Akaka said.

"It is clear to me that the desired level of cooperation and collaboration between the DOD and the VA has not been achieved," Akaka said.

The problems with the VA have grown more intense, Akaka said, because now the VA must deal with National Guard or reserve troops wounded or injured in Iraq or Afghanistan.

"I want to know what is happening with members of the guard and reserves," Akaka said during yesterday's hearing.

Also, Akaka said he would explore how the VA is handling the aging population of World War II vets.

Attending the hearing was Sen. Barack Obama, D-III., who said he wanted the committee to focus the VA's attention on helping homeless veterans.

Last year Akaka and the committee held four hearings in Hawaii, which Akaka said resulted in the VA adding \$1 million to "mental health initiatives" in Hawaii. As chairman, Akaka is expected to increase committee visits to Hawaii.

While the House yesterday was passing a bill to implement the recommendations of the 9/11 Commission, Akaka participated in Senate hearings on that issue.

He said the commission had noted that terrorist organizations such as al-Qaida know more about the United States than we know about Arab or Muslim culture. Akaka said the United States at least should improve foreign language studies.

"Following 9/11, the FBI scrambled to find agents capable of speaking Iraqi. The ability of federal agents to recruit agents with language skills is directly tied to the ability of U.S. schools to teach foreign languages," Akaka said.

Appearing before the committee yesterday was New York Mayor Michael Bloomberg, who responded to Akaka by saying the New York Police Department has more officers who speak Arabic than does the federal government.

"You couldn't be more right, Senator Akaka," Bloomberg said. He joked that perhaps the federal government could hire the NYPD to help with Arabic translations.

FDA to sweep unapproved drugs off the market

01/09/07 – By Rita Rubin, USA Today

ROCKVILLE, Md. — A Food and Drug Administration official on Tuesday told representatives of 65 companies selling unapproved drugs that the agency plans to step up efforts to remove such products from the market.

"We do intend to accelerate removal of unapproved drugs this year," Deborah Autor, director of the FDA's Office of Compliance, said at a day-long workshop about the routes makers of unapproved drugs can take to get the agency's blessing and avoid expulsion from the market.

In September, a USA TODAY cover story pointed out that many doctors, patients and pharmacists are unaware that some medications on the market — nearly 2% of prescription drugs, according to the FDA — have never been scrutinized by the agency.

The USA TODAY story spurred Sen. Chuck Grassley, R-Iowa, to write a letter to FDA Commissioner Andrew von Eschenbach asking for more information about how unapproved drugs end up on the market.

They're sold as prescription and over-the-counter products for a range of ailments, including colds and coughs, hot flashes and pain. But consumers cannot be sure whether such medications are effective, let alone safe, Autor says.

Companies that market unapproved drugs, many of which have been sold for years, argue that their products have stood the test of time. But, said Robert Temple, director of the FDA's Office of Medical Policy, "the fact that there's long-term use really doesn't tell you anything."

Temple cited the case of anti-cholinergic sedatives, which had been used for years to treat irritable bowel syndrome. Eventually, the drugs were tested for that condition in large clinical trials, Temple said, and "every one of them failed completely."

When one audience member asked why the FDA doesn't just ban all unapproved drugs, Autor said the agency instead is taking a "concerted and concentrated approach." She said, "We are constantly evaluating potential targets."

One priority is getting unapproved versions of approved drugs off the market, Autor said.

URL/Mutual Pharmaceuticals of Philadelphia waited nearly a year for the FDA to remove unapproved quinine products from the market before launching Qualaquin, its approved version of the drug, in July. Qualaquin is prescribed for malaria, but the unapproved versions were marketed for leg cramps and other uses as well as malaria.

URL filed court motions in August against seven makers of unapproved quinine sulfate products, and all but one agreed to stop selling them by mid-November. Finally, the FDA announced last month that, because of safety concerns, it had ordered all unapproved quinine products off the market. Since 1969, the FDA said, unapproved quinine products had been linked to 93 deaths.

Dental X-rays can spot osteoporosis Study suggests simple, inexpensive way to detect bone-thinning disease 01/10/07 - Reuters

NEW YORK - A computer program that analyzes routine dental X-rays could offer a simple, cheap way to detect the bone-thinning disease osteoporosis, new research suggests.

British researchers found that a software program they developed was able to spot signs of declining bone density in dental X-rays of the lower jaw — a potential sign of osteoporosis.

The findings, they report, suggest that routine dental X-rays could provide an inexpensive way to provide wide screening of older adults for osteoporosis. Those with signs of bone thinning in the jaw could be referred for more expensive osteoporosis testing.

In the U.S., the Preventive Services Task Force recommends that all women age 65 or older be screened for osteoporosis — the "gold standard" for screening is a relatively expensive test called dual energy X-ray absorptiometry (DXA). Medicare will pay for this test every two years.

In the United Kingdom, the national health system currently has no program for osteoporosis screening.

That means many people with the disease — most often older women — won't know they have it until they suffer a fracture, said Dr. Hugh Devlin of the University of Manchester, the lead author on the new study.

The study findings, published online in the journal Bone, are based on bone X-rays of 652 European women 45 to 70. All of the women underwent DXA, as well as panoramic dental X-rays, which show the whole jaw.

The DXA tests found osteoporosis in the hip or spine in 140 women. Analysis of dental X-rays picked up more than half of these cases, the researchers found.

More work is needed before dental X-rays become part of osteoporosis screening, Devlin said. "We want to find out the attitude of patients and doctors to this new role of dentists identifying patients they suspect of being at high risk of osteoporosis," he noted.

The next step, according to Devlin, will be for an X-ray equipment company to take to the idea and integrate the software into its products.

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Next month, the Senate is expected to do the same, as it did last year.

And all indications are that soon after that, Bush will, for the second time, veto the bill.

But the final outcome of this year's emotional fight over the science and ethics of stem cell research is not as predictable as it may seem, said scientists and congressional strategists on both sides of the issue.

Opponents of the research say they have never been stronger, not only because of the ongoing support of the president but also because several recent studies have suggested that non-embryonic cells have significant medical promise that may rival that of embryonic cells.

Proponents, however, have a new ace up their sleeve as well: the political shifts wrought by voters in November. With stem-cell-friendly Democrats in the majority for the first time since the cells were discovered in 1998, supporters of the research will be able to work Congress's complex rules in their favor.

"This is not a 'one bill and you're out,' but a two-year time frame with potentially multiple legislative possibilities," said a research supporter involved in Capitol Hill strategizing, speaking on the condition of anonymity because he is not authorized to comment publicly.

"They can stretch it out," the strategist said, so Bush and his backers in Congress must keep saying no to research that the public says it strongly supports. The research advocates "can make it as painful as possible."

Congressional leaders driving the legislation say they hope to avoid all-out war. Compromise language "is welcome," Rep. Diana DeGette (D-Colo.) said Tuesday at a news briefing, conceding that Bush has rebuffed all entreaties so far.

But if it comes to war, members of Congress and aides from both parties said, supporters have many options not available to them last year. They range from subtle moves that could enhance the odds of overriding a veto to heavy-handed tactics such as attaching the bill to must-pass budget legislation.

"I'm confident we'll have a veto-proof bill this time," said Sen. Arlen Specter (R-Pa.), one of three high-powered Republican supporters of stem cell research who attended the Tuesday briefing. In an odd Washington moment, all three seemed briefly grateful that the Democrats were back in charge.

Sen. Tom Harkin (D-lowa), who has led the stem cell charge in the Senate along with Specter, agreed. "One way or another, we're going to get this done this year," he said yesterday in a meeting with Washington Post editors and reporters.

At issue are five-day-old human embryos that are about the size of the period at the end of this sentence. Stem cells from those embryos show promise for their ability to treat a wide array of diseases and for the secrets they may reveal about one of biology's biggest mysteries: how a fertilized egg cell can become a fully formed person.

Under a policy initiated by Bush on Aug. 9, 2001, taxpayer dollars can be used to study only those cells derived from embryos that were already destroyed by that date -- about 21 colonies of cells out of almost 400 that exist today.

The new legislation would expand that pool by allowing funding of work on cells from embryos slated for disposal at fertility clinics and donated by parents. It would also impose some of the first federal ethics rules on stem cell research, including a provision banning the sale of embryos.

The bill has the support of 66 senators, say Senate leaders, and more than the 238 representatives who voted for it in 2005.

Opponents, however, call the research an assault on nascent human life and an abandonment of society's most vulnerable, and there were reports last night that they might try to block passage in the House by attaching "poison pill" language that many stem cell proponents would have a hard time supporting.

Recent news about other, less controversial kinds of cells with traits resembling those of embryonic cells has already complicated the legislative push.

Opponents have long argued that "adult stem cells," various kinds of which exist in bone marrow, umbilical cords and other tissue, are suitable substitutes for embryonic cells. The true potential of those cells remains mostly unknown. But this week researchers published some of the strongest evidence yet that non-embryonic cells -- in this case, cells in the amniotic fluid of pregnant women -- might have much the same capacity as embryo cells.

In an unusual move, the White House itself touted the news Monday in a flurry of "In Case You Missed It" e-mails, as did activist groups such as the National Right to Life Committee.

"We applaud the work of those researchers who continue to look for ethical stem cell research alternatives that do not require destroying human life, and we call on Congress to support such ethical alternatives," the group's legislative director, Douglas Johnson, said in a statement.

But scientist after scientist said that, attractive as the new findings are, they remain preliminary and unconfirmed. Moreover, the work is eight years behind the progress already made with embryonic cells, which researchers hope to start testing in patients by next year.

Even the scientist who led the amniotic cell study released a letter Tuesday warning against using his work as an excuse to vote against broader stem cell funding.

"I understand that some may be interpreting my research as a substitute for the need to pursue other forms of regenerative medicine therapies, such as those involving embryonic stem cells," Anthony Atala of Wake Forest University School of Medicine wrote in a letter to DeGette and cosponsor Rep. Michael N. Castle (R-Del.). "I disagree with that assertion. . . . It is essential that

National Institute[s] of Health-funded researchers are able to fully pursue embryonic stem cell research."

One strategy being considered by supporters is to add mollifying amendments to the Senate version, Castle said -- an option that was not open to the Senate last year under the arrangement brokered by then-Majority Leader Bill Frist (R-Tenn.). Although specific provisions have not been discussed in detail, Castle said senators could add funding for programs that donate unwanted frozen embryos to infertile women, a favorite program of Bush's; require extra ethical oversight for stem cell research; or beef up support for parallel studies of non-embryonic cells.

Procedurally, if a veto does come, supporters would benefit if the Senate first modified the bill. That is because full passage would require a House-Senate conference, and under congressional rules the Senate would then control the bill. That means the first attempt to override the veto would be in the Senate -- where the votes are believed to be within reach -- instead of the House, which was first to vote on an override last year.

The House effort failed and would have a difficult time succeeding this year. But inspired by a Senate override and perhaps appeased by amendments in conference, some members who vote against the bill today could feasibly vote yes after a veto. Even if the override failed there, the bill would have gotten further than last time, aides say.

At that point, several strategies could come into play, including attaching it to a must-pass bill or holding hearings featuring desperate patients, which might embarrass the White House -- all possible because Democrats now chair the relevant committees. Subsequent votes could follow, forcing a string of vetoes.

"There is nothing wrong with this bill," said Sen. Dianne Feinstein (D-Calif.). "We should pass this bill again and again and again, until we get a president who will sign it."